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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,478	11/14/2000	James A. Laugharn Jr.	07985-012002	6793
7590	07/16/2002		EXAMINER	
Fish & Richardson 225 Franklin Street Boston, MA 02110-2804			WILSON, JAMES O	
		ART UNIT	PAPER NUMBER	
		1623		
		DATE MAILED: 07/16/2002		

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/530,478</b>	Applicant(s) <b>Laugharn, Jr. et al.</b>
Examiner <b>James O. Wilson</b>	Art Unit <b>1623</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Apr 19, 2002

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-5, 9, 11, 13-17, 59-67, 69-80, 82-84, 91-95, and 97-102 is/are pending in the application.

4a) Of the above, claim(s) 1-5, 9, 11, 13-17, 59-67, 69-71, 93-95, 97, and 102 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 72-80, 82-84, 91, 92, 98, and 99 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- Notice of References Cited (PTO-892)
- Notice of Draftsperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- Notice of Informal Patent Application (PTO-152)
- Other: \_\_\_\_\_

Art Unit:

The following Office Action is in response to the April 19, 2002 Election without traverse of the invention of Group V, which is claims 72-80, 82-84, 91-92 and 98-99. An action on the merits of pending claims 72-80, 82-84, 91-92 and 98-99 is contained herein below.

Claims 1-5, 9, 11, 13-17, 59-67, 69-71, 93-95, 97 and 100-102 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 10, filed April 19, 2002.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 72-80, 82-84, 91-92 and 98-99 are rejected under the judicially created doctrine of double patenting over claims 1-9 of U. S. Patent No. 6,120,985 ("985 Patent), since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

Art Unit:

**Determining the scope and contents of the prior art**

It is noted that both the instant application and the '985 Patent are drawn to processes which contain two of the same steps,

- 1) exposing cells to an elevated pressure to obtain lysed cells
- 2) separating molecules.

Repeating the steps, the rate of variable pressure increases, the temperature range for the process, the value in psi's of the minimal elevated pressure, the type of cell to be lysed and subsequent purification steps are all seen to be substantially overlapping between the '985 Patent and the instantly claimed application. The patent discloses repetition of the steps including altering temperature and/or pressure, see claims 1 and 2. The rate of variable pressure increases wherein the final value is achieved in less than 1 second (which includes 0.1 seconds), The temperature for the lysis process to be -20 C or higher (still subzero), the disclosure that the elevated pressure in psi's is between 28 psi's and 75,000 psi's (which includes 500 psi's) .

**Ascertaining the differences between the prior art and the claims at issue**

The '895 Patent's claims include additional steps which are not seen to be necessarily excluded from the methodological steps in the claims of the application, since both the patent and the application employ the term "comprises", which provides for the substantial overlap. The temperature of the process of the '985 patent is seen to overlap with that of the application wherein the temperature is not mentioned at all. The temperatures in the processes for lysing cells in the '985 Patent and in the instant application are divergent when the application specifically claims 50 C to 90 C. Even though the claims of the patent do not set forth a specific separation step, the examiner interprets both processes to necessarily include a molecule separation step because effective lysis will provide for a "physical separation of molecules" via sedimentation, into lysed and non-lysed portions. The process steps of the patent do indeed encompass the process steps of the application and the recitation of a step in the instant application which is inherently

Art Unit:

met by the action requisite performed by a step in the process of the '985 patent is not seen to be a critical difference.

**Resolving the level of ordinary skill in the pertinent art**

It would have been obvious to one having ordinary skill in this art at the time the invention was made to use pressure and/or temperature variability to lyse cells and to subsequently separate the lysate's components as applicant's have done with the '985 Patent before them. The substantial degree of overlap between the process step claims in the instant application and in the '985 Patent indeed necessitates the obviousness-type double patenting rejection set forth herein. The differences include non-critical limitations which are not specifically excluded in the open-ended process of the instant application or in the '985 Patent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 74, 77 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

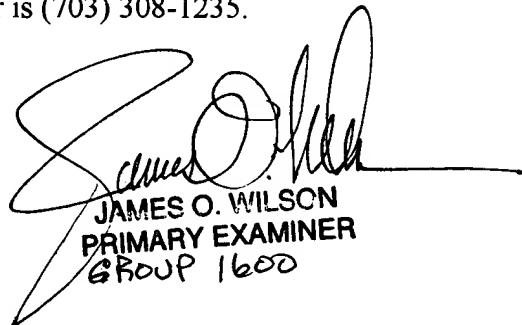
The procedural step which requires "extraction of molecules" alluded to in claims 74 and 77 is not seen to be set forth in claim 72. In fact, this terminology and intended action is seen to lack antecedent basis.

Art Unit:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James O. Wilson, Primary Examiner in Art Unit 1623 whose telephone number is (703) 308-4624. The examiner can normally be reached on Monday-Friday from 10:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached on (703) 308-4532. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



JAMES O. WILSON  
PRIMARY EXAMINER  
GROUP 1600